ORTHOFIX

SKYHAWK™ Interbody Fusion System

5.0 510(k) Summary

MAY 2 7 2014

Date Prepared: May 22, 2014

Purpose for Submission: New product offering

Sponsor:
Orthofix
Troy Brooks, RAC
3451 Plano Parkway
Lewisville, Texas 75056
214-937-2047

Device Name: SKYHAWK™ Interbody Fusion System

Product Code: MAX

Classification: Class II – 21 CFR § 888.3080 – Intervertebral Body Fusion Device

Predicate Device:
Orthofix FORZA Spacer System – K103111
NuVasive CoRoent System – K071795
Medtronic PERIMETER Interbody Fusion Device – K131669

Device Description: The SKYHAWK Interbody Fusion System consists of implants, trials, and instruments. The SKYHAWK Interbody Fusion System is comprised of a variety of implants fabricated and manufactured from polyetheretherketone (PEEK Optima LT1) as described by ASTM F2026 with tantalum markers as described by ASTM F560. PEEK is utilized due to its radiolucent properties, which aids the surgeon in determining if fusion in the operative site has occurred. Since PEEK is transparent in x-rays, tantalum marker pins are inserted into the implants in order to give surgeons a visual aid in determining the location of the implants, both intra and postoperatively.

The SKYHAWK Interbody Fusion System implants are offered in parallel and lordotic profiles to restore the natural curvature of the spine; the device may be implanted using a lateral or anterolateral approach.

The SKYHAWK Interbody Fusion System implants, trials and instruments are provided non-sterile. They require sterilization prior to use.

Intended Use: The SKYHAWK Interbody Fusion System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s).

The SKYHAWK Interbody Fusion System is designed for use with autogenous bone graft to facilitate fusion. The system is also intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the SKYHAWK Interbody Fusion System.

Non-Clinical Testing:	Mechanical testing of the SKYHAWK Interbody Fusion System consisting of static and dynamic axial compression testing, static and dynamic compression shear testing, and static subsidence testing was conducted in accordance with ASTM F2077-11 *"Test Methods for Intervertebral Body Fusion Devices" and* ASTM F2267-04 *"Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device under Static Axial Compression."* Test results demonstrate that the SKYHAWK Interbody Fusion System is substantially equivalent to the predicate device.
Conclusion:	Based upon similarities in design, materials, intended use, indications for use and the results of mechanical testing, the SKYHAWK Interbody Fusion System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 27, 2014

Orthofix, Incorporated
Troy Brooks, RAC
Senior Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

Re: K140709
Trade/Device Name: SKYHAWK™ Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 31, 2014
Received: April 1, 2014

Dear Mr. Brooks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): K140709

Device Name: **SKYHAWK™ Interbody Fusion System**

Indications for Use:

The SKYHAWK Interbody Fusion System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s).

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices